



THE MAINE HEART CENTER

At Maine Medical Center

# **Should the ICEBP Endorse the Shann “Guidelines”?**

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Associate Vice President of Cardiac  
Services  
Director of Cardiovascular Perfusion  
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# **Should the ICEBP Endorse the Shann Evidence Based Review of Practice?**

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## Cardiopulmonary Support and Physiology

# An evidence-based review of the practice of cardiopulmonary bypass in adults: A focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response

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See related editorial on page 223.



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Cardiopulmonary bypass (CPB) can be used during cardiac surgery to oxygenate and subsequently recirculate blood that has been diverted from the heart and lungs. The practice of CPB has changed—and continues to change—dramatically since its advent in the 1950s. Although structured reviews of the evidence supporting the practice of cardiac surgery have been in the literature for more than a decade and continue to be refined in the wake of new and emerging evidence,<sup>1,11,12</sup> additional targeted reviews, focusing on issues such as minimizing the effect of the inflammatory response or minimizing neurologic injury, are warranted.<sup>13-15</sup> Previous attempts, by Edwards and colleagues<sup>16</sup> and Bartels and associates,<sup>17</sup> at synthesizing the evidence base to support the principles of CPB have selectively reviewed the cardiac surgery literature or focused on unique patient populations. Additionally, the development of these reviews has not involved all members of the clinical team, most notably the individuals tasked with operating the CPB circuit. This gap in knowledge is in stark contrast with the shared goal of the cardiac team, namely to improve the conduct of CPB to reduce the patient's risk of adverse outcomes caused by cardiac surgery.

Despite a preponderance of evidence supporting key principles of managing safe and effective CPB practice, wide variation in the use of technology and techniques for conducting CPB persists regionally and nationally.<sup>18,19</sup> Variations in practice have previously been shown to be associated with increased costs, lengths of stay, neurologic injury, and mortality.<sup>1-3,8,9,10,11</sup> This variation might be attributed to clinical uncertainty or institutional or local practice standards. To reduce this unwanted practice variation, we must provide our clinical colleagues with critically evaluated and evidence-based review for conducting CPB.

What follows is an evidence-based review for conducting safe, patient-centered,

## Editor's Note: Consensus statements as a **variant** of classical statistical methods

Andrew S. Wechsler, MD, Editor

See related article on page 283.

**T**he *Journal* has used editorials as teaching exercises as new methods of statistical analysis have been introduced as tools for understanding and testing data acquired during investigations. We have discussed propensity analysis, the use of actual and actuarial methods, and meta-analyses. There are, however, instances in which traditional statistical analyses provide steps along the path to understanding pieces of a larger puzzle but fall short of helping us achieve a broader vision of that which we are studying. Oftentimes, traditional statistical analyses yield conflicting conclusions to the same issues under study. This is not the consequence of flawed statistical method, but rather the consequence of subtle differences in study designs. Subjective terms such as context and nuance facilitate the transition from results of individual studies to broad applicability. In other words, an interpretative component allows us to apply many individual, but different, studies to everyday practice.

It is in this spirit that the work of Likosky and his colleagues is published in this issue of the *Journal* on page 283. The method used is "consensus," which

“This method incorporates a technique that has been occasionally described as “eminence” rather than “evidence,” and the final product is a combination of the two.”

“Consensus uses grades of evidence but only after those providing the consensus opinions have been free to discard or incorporate specific scientific contributions.”

**Andrew Wechsler**

“It is in this spirit that this manuscript is published. It is definitely not an attempt to suggest guidelines but rather an opportunity to demonstrate another mechanism of analysis.”

**Andrew Wechsler**  
**Editor JTCVS**

# Development of Guidelines

<http://circ.ahajournals.org/manual>

- Determine the guideline scope
- Define and conduct appropriate and comprehensive literature searches
- Sort and evaluate the evidence
- Synthesize and interpret the evidence

## Applying Classification of Recommendations and Level of Evidence "SIZE of TREATMENT EFFECT"

"Estimate of Certainty (Precision) of Treatment Effect"

	Class I <i>Benefit &gt;&gt;&gt; Risk</i>  Procedure/Treatment <b>SHOULD</b> be performed/administered	Class IIa <i>Benefit &gt;&gt; Risk</i> <i>Additional studies with focused objectives needed</i>  <b>IT IS REASONABLE</b> to perform procedure/administer treatment	Class IIb <i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; Additional registry data would be helpful</i>  Procedure/Treatment <b>MAY BE CONSIDERED</b>	Class III <i>Risk ≥ Benefit</i> <i>No additional studies needed</i>  Procedure/Treatment should <b>NOT</b> be performed/administered <b>SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL</b>
Level A <i>Multiple (3-5) population risk strata evaluated*</i>  <i>General consistency of direction and magnitude of effect</i>	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment is useful/effective</li> <li>Sufficient evidence from multiple randomized trials or meta-analyses</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation in favor of treatment or procedure being useful/effective</li> <li>Some conflicting evidence from multiple randomized trials or meta-analyses</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation's usefulness/efficacy less well established</li> <li>Greater conflicting evidence from multiple randomized trials or meta-analyses</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment not useful/effective and may be harmful</li> <li>Sufficient evidence from multiple randomized trials or meta-analyses</li> </ul>
Level B <i>Limited (3-3) population risk strata evaluated*</i>	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment is useful/effective</li> <li>Limited evidence from single randomized trial or non-randomized studies</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation in favor of treatment or procedure being useful/effective</li> <li>Some conflicting evidence from single randomized trial or non-randomized studies</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation's usefulness/efficacy less well established</li> <li>Greater conflicting evidence from single randomized trial or non-randomized studies</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment not useful/effective and may be harmful</li> <li>Limited evidence from single randomized trial or non-randomized studies</li> </ul>
Level C <i>Very limited (1-2) population risk strata evaluated*</i>	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment is useful/effective</li> <li>Only expert opinion, case studies, or standard-of-care</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation in favor of treatment or procedure being useful/effective</li> <li>Only diverging expert opinion, case studies, or standard-of-care</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation's usefulness/efficacy less well established</li> <li>Only diverging expert opinion, case studies, or standard-of-care</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment not useful/effective and may be harmful</li> <li>Only expert opinion, case studies, or standard-of-care</li> </ul>
<b>Suggested phrases for writing recommendations</b>	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

\* Data available from clinical trials or registries about the usefulness/efficacy in different sub-populations, such as gender, age, history of diabetes, history of prior MI, history of heart failure, and prior aspirin use.

- 1. pH Management** The clinical team should manage adult patients undergoing moderate hypothermic CPB with alpha-stat pH management. (Class I, Level A)
- 2. Avoidance of Hyperthermia** Limiting arterial line temperature to 37°C might be useful for avoiding cerebral hyperthermia. (Class IIa, Level B) “Coupled temperature” ports for all oxygenators should be checked for accuracy and calibrated.
- 3. Return of Pericardial Suction Blood** Direct reinfusion to the CPB circuit of unprocessed blood exposed to pericardial and mediastinal surfaces should be avoided. (Class I, Level B) Blood cell processing and secondary filtration can be considered to decrease the deleterious effects of reinfused shed blood. (Class IIb, Level B)
- 4. Aortic Assessment** In patients undergoing CPB at increased risk of adverse neurologic events, strong consideration should be given to intraoperative TEE or epiaortic ultrasonographic scanning of the aorta: (1) to detect nonpalpable plaque (Class I, Level B) and (2) for reduction of cerebral emboli (Class IIa, Level B).
- 5. Arterial Filtration** Arterial line filters should be incorporated in the CPB circuit to minimize the embolic load delivered to the patient. (Class I, Level A).

- 6. Maintenance of Euglycemia** The clinical team should maintain perioperative blood glucose concentration within an institution's normal clinical range in all patients, including nondiabetic subjects. (Class I, Level B)
- 7. Reduction of Hemodilution** Efforts should be made to reduce hemodilution, including reduction of prime volume, to avoid subsequent allogeneic blood transfusion. (Class I, Level A)
- 8. Attenuation of the Inflammatory Response** Reduction of circuit surface area and the use of biocompatible surface–modified circuits might be useful- effective at attenuating the systemic inflammatory response to CPB and improving outcomes. (Class IIa, Level B)

## Cardiopulmonary Bypass Recommendations in Adults: The Northern New England Experience

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# **Perioperative Blood Transfusion and Blood Conservation in Cardiac Surgery: The Society of Thoracic Surgeons and The Society of Cardiovascular Anesthesiologists Clinical Practice Guideline\***

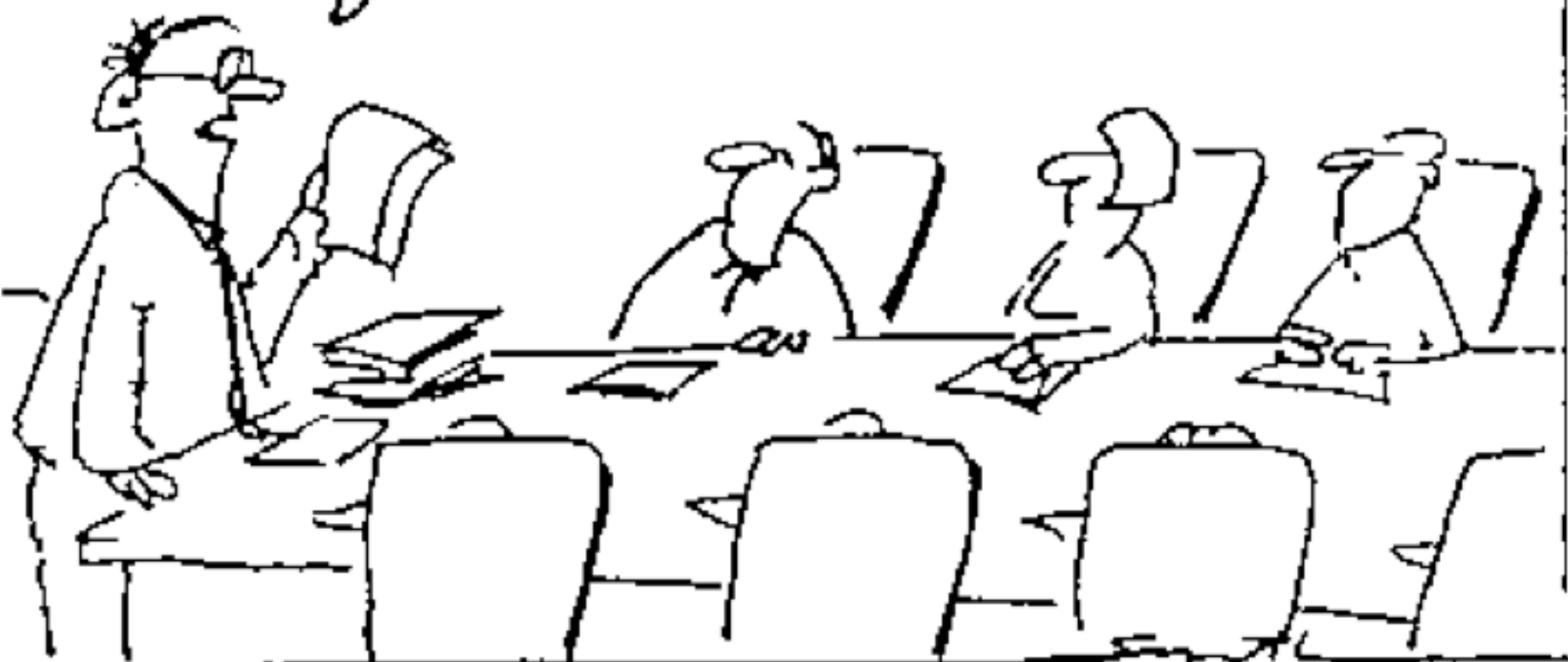
The Society of Thoracic Surgeons Blood Conservation Guideline Task Force:

Victor A. Ferraris, MD, PhD (Chair), Suellen P. Ferraris, PhD, Sibiu P. Saha, MD, Eugene A. Hessel II, MD, Constance K. Haan, MD, MS, B. David Royston, MD, Charles R. Bridges, MD, ScD, Robert S. D. Higgins, MD, George Despotis, MD, and Jeremiah R. Brown, PhD

The Society of Cardiovascular Anesthesiologists Special Task Force on Blood Transfusion:

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THE LATEST RESEARCH SHOWS THAT  
WE REALLY SHOULD DO SOMETHING  
WITH ALL THIS RESEARCH





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# **Perfusion Guidelines: Confessions of a two time Loser**

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# Why I am a two time loser?

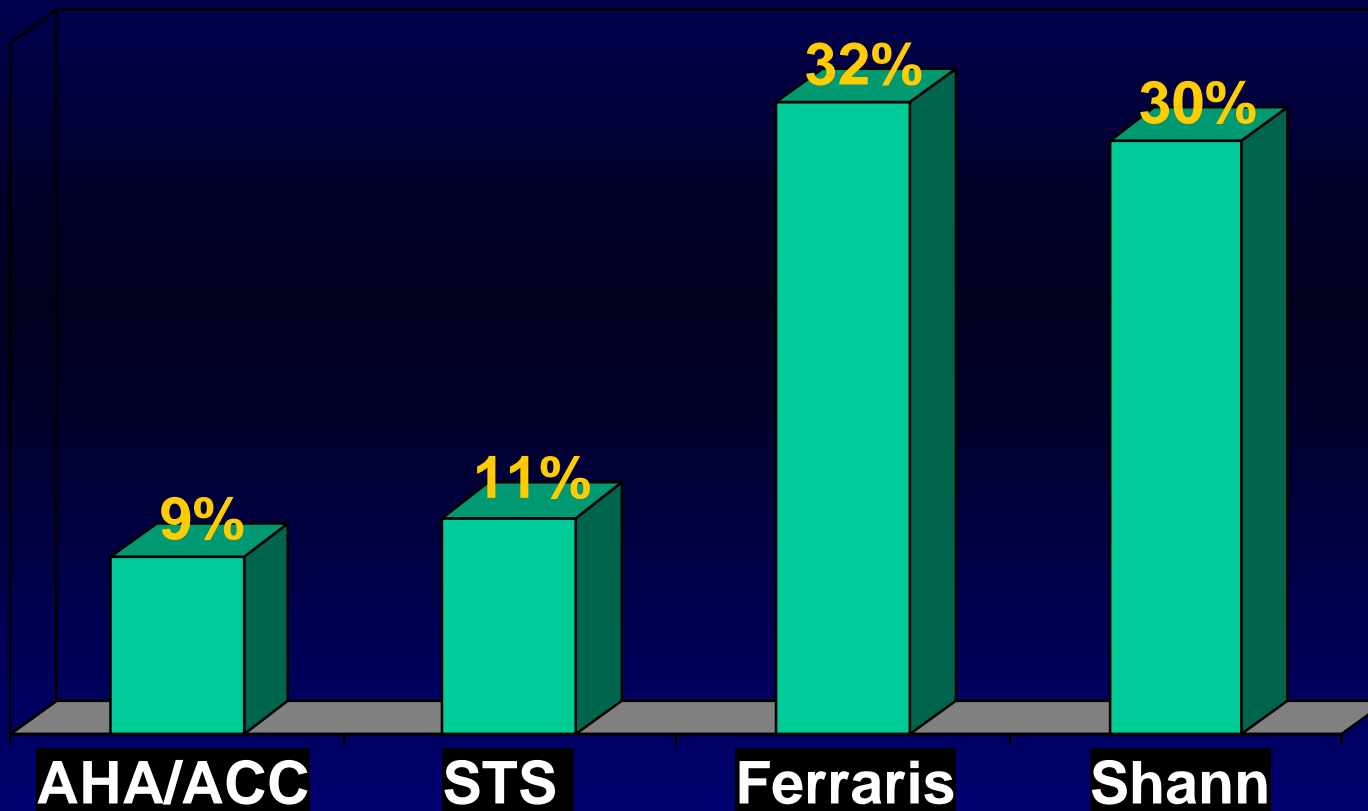
- It was a lot of work and I couldn't keep up
- I worried about bias in the group
- Couldn't totally agree with some of the recommendations

**Do not adopt this Evidence Based Review. Rather update and publish a guideline.**

# Guidelines

## Are we reading them?

% that have read Guidelines



Sample size 120 CCPS